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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/981,483 | 10/16/2001 | Dirk Boecker | 10003016 | 6038 |

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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
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| EXAMINER | |
|---|---|
| FOREMAN, JONATHAN M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3736 | |

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|---|---|---|
| | 09/981,483 | BOECKER ET AL. |
| | Examiner | Art Unit |
| | Jonathan ML Foreman | 3736 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 October 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *21,42 and 43* is/are allowed.

6)☐ Claim(s) *1-5,8-10,12-20 and 22-41* is/are rejected.

7)☒ Claim(s) *6,7 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: Figure 2 has the reference sign "200". A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 – 5, 8 – 10, 12 – 20, 22 – 26, 29 and 32 – 39 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,772,586 to Heinonen et al.

In regards to claims 1 – 5, 8, 9, 12 – 20, 22 and 32 – 39, Heinonen et al. discloses applicant's claimed invention(Figure 2 – 4) including a sampling module comprising a lancet (19), a driving mechanism (Col. 5, lines 20 – 22), and a sample port (Col. 6, lines 2 – 3) for receiving body fluid directly from a punctured tissue; an assay sensor module (Col. 5, line 66 – Col. 6, line 6) housed in a cartridge, the cartridge having an interface with the sample port and a passageway to transport the body fluid to at least one assay sensor (Col. 5, line 66 – Col. 6, line 6); and a communication module adapted to communicate with an information management system (Col. 3, line 65 – Col. 4, line 15). The communication module has a radio frequency transmitter to transfer information to a remote location and a receiver to communicate with a remote database (Col. 2, lines 47 – 50; Col. 4, lines 28

– 44). The analytical detector module is adapted to couple with the cartridge via standard interface (Col. 4, lines 63 – 67). The information storage unit can store information locally (Col. 5, lines 53 – 58). The information management system is a centralized means for collecting and processing information. Historical information can be displayed locally (Col. 5, lines 53 – 58). The information system comprises a system for brokering medical data and a system for patient management (Col. 4, lines 45 – 53). The communication module has at least one of the following: a processor, display, RF chip, antenna, operating system, RAM DRAM, or a PCMCIA interface.

In regards to claims 10, 23 – 26 and 29, Heinonen et al. discloses applicant's claimed method including obtaining body fluid directly from a tissue punctured with a lancet driven by a driving mechanism outward from a cartridge by a lancet driver (Col. 5, lines 21 – 27); housing the fluid in a cartridge having an assay sensor module (Col. 5, line 66 – Col. 6, line 66); position the cartridge in an analytical detector module; obtaining information from the analytical detector module; displaying the information locally on a display (Col. 5, lines 53 – 58); and transferring the information to a remote location via a communication module (Col. 3, line 65 – Col. 4, line 44). Heinonen et al. discloses a plurality of assay sensors, each performing the same analysis on the body fluid (Col. 5, lines27 – 29). The communication module has a transmitter.

## *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,772,586 to Heinonen et al.

In regards to claims 27 and 28, Heinonen et al. discloses a plurality of assay sensors for providing analysis for glucose. Heinonen et al. fails to teach performing a variety of different analysis on the body fluid. Heinonen et al. does disclose that other measurement s could be performed in addition to the monitoring of glucose (Col. 3, lines 59 – 64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the assay sensors as disclosed by Heinonen et al. to perform a variety of different analysis in order to expand the capabilities of the device and to allow better patient monitoring.

Claims 30, 31, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,772,586 to Heinonen et al. as applied to claims 23 and 32 above, and further in view of U.S. Patent Application Publication No. 2003/0083685 to Freeman et al.

In regards to claims 30, 31, 40 and 41, Heinonen et al. discloses a lancet being driven by a driver (Col. 5, lines 21 – 22), but fails to disclose the driver being an electromechanical or an electrical driver. Freeman et al. teaches a lancet being driven by a driver, wherein the driver can be either a controllable driver or non-controllable driver any mechanical, such as spring or cam driven, or electrical, such as electromagnetically or electronically driven, means for advancing, stopping, and retracting the lancet [0229]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the driver as disclosed by Heinonen et al. with an electromechanical or electrical driver, in that Freeman et al. teaches the driver disclosed by Heinonen et al. and electrical drivers as being functionally equivalent and therefore interchangeable.

## *Allowable Subject Matter*

6. Claims 21, 42 and 43 are allowed. Claims 6, 7 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

## *Response to Arguments*

7. Applicant's arguments filed 10/16/03 have been fully considered but they are not persuasive. Applicant has asserted that Heinonen et al. does not disclose a sampling module having a lancet, a driving mechanism, and a sample port, wherein the sampling port receives body fluid directly from a tissue punctured with the lancet. However, Heinonen et al. does disclose a sampling module (11) having a lancet, a driving mechanism, and a sample port, wherein the sampling port receives body fluid directly from a tissue punctured with the lancet (Col. 5, lines 21 – 39). The sampling port is capable of receiving body fluid directly from the punctured tissue by merely touching the sampling port to the area where the tissue was lanced. Additionally applicant has asserted that Heinonen et al. does not disclose a sampling module comprising a sample port, the sampling module being housed in a cartridge. However, Heinonen et al. does disclose a sampling module comprising a sample port, the sampling module (11) being housed in a cartridge (Col. 4, lines 63 – 67).

8. Per applicant's request that the Examiner cite a prior art reference to support the assertion made by the Examiner regarding the substitution of the mechanical driver disclosed by Heinonen et al. for an electrical driver, the examiner cites U.S. Patent Application Publication No. 2003/0083685 to Freeman et al. Freeman et al. teaches that such a substitution is known in the art [0229].

*Conclusion*

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

JMLF
January 12, 2004

MAX F. HINDENBURG
PATENT EXAMINER
TECHNOLOGY CENTER 3700